EXHIBIT B

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SUPERIOR COURT OF CALIFORNIA, COUNTY OF SANTA CLARA COURTHOUSE

23CV415803

ANTONIO PINA,

Plaintiff,

vs.

COVIDIEN, INC., COVIDIEN, LTD., COVIDIEN PLC, COVIDIEN LLC, COVIDIEN HOLDING INC., MEDTRONIC USA, INC., MEDTRONIC PLC, TYCO HEALTHCARE GROUP LP (d/b/a Covidien, LP), TYCO INTERNATIONAL LTD., TYCO INTERNATIONAL GROUP S.A., SURGICAL SOLUTIONS GROUP, UNITED STATES SURGICAL CORP., a division of TYCO HEALTHCARE GROUP LP, SOFRADIM PRODUCTION SAS, SOFRADIM CORP, JAMES NATHAN LAU M.D., STANFORD HOSPITAL, and DOES 1 through 100

Defendants.

Case No.:

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

(1) Strict Products Liability - Inadequate Warning
(2) Negligence
(3) Fraudulent Concealment
(4) Express Warranty
(5) Medical Negligence

Plaintiff ANTONIA PINA hereby sues defendants COVIDIEN, INC., COVIDIEN, LTD., COVIDIEN PLC, COVIDIEN LLC, COVIDIEN HOLDING INC., MEDTRONIC USA, INC., MEDTRONIC PLC, TYCO HEALTHCARE GROUP LP (d/b/a Covidien, LP), TYCO INTERNATIONAL LTD., TYCO INTERNATIONAL GROUP S.A., SURGICAL SOLUTIONS GROUP, UNITED STATES SURGICAL CORP., a division of TYCO HEALTHCARE GROUP

LP, SOFRADIM PRODUCTION SAS, SOFRADIM CORP, JAMES NATHAN LAU M.D., STANFORD HOSPITAL, and DOES 1 through 100 (collectively referred to as "Defendants"), and each of them, and alleges as follows:

PARTIES

1. Plaintiff Antonia Pina at all times relevant to this matter was domiciled and resided in and continues to be domiciled and reside in King City, California. Mr. Pina underwent hernia repair surgery and placement of a Covidien Parietex Composite Open Skirt Mesh (referred to as "mesh," "device" or "product" hereinafter) on July 9, 2018.

2. Defendant COVIDIEN, INC. ("Covidien Inc.") is a Delaware corporation with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices and facilities in Bedford and Waltham, Middlesex County, Massachusetts, and Boston, Suffolk County, Massachusetts. All acts and omissions of Covidien Inc. as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh devices at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, Covidien Inc. did business in California.

3. Defendant COVIDIEN, LTD. ("Covidien ltd.") is a Bermuda public limited company with its principal place of business in Bermuda, and offices in Bedford and Waltham, Middlesex County, Massachusetts. All acts and omissions of Covidien ltd. as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh devices at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, Covidien ltd. did business in California.

4. Defendant COVIDIEN PLC ("Covidien plc") is an Irish public limited company with its principal place of business in Massachusetts at 15 Hampshire Street, Mansfield, Bristol

County, Massachusetts, and offices in Bedford and Waltham, Middlesex County, Massachusetts. All acts and omissions of Covidien plc as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh products at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, Covidien plc did business in California.

5. Defendants, COVIDIEN HOLDING INC., ("COVIDIEN") is a corporation that is incorporated under the laws of the State of Delaware. COVIDIEN has its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices in Bedford and Waltham, Middlesex County, Massachusetts. COVIDIEN focuses its business on products in key surgical specialties, including hernia repair, laparoscopic instrumentation, embolization device, pharmaceuticals, and medical supplies. Covidien is registered to conduct business in California. At all times material hereto, Covidien did business in California.

6. Defendant COVIDIEN, LLC (d/b/a Covidien LP, f/k/a Tyco Healthcare Group LP)), is a Delaware limited partnership with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts, and offices in Bedford and Waltham, Middlesex County, Massachusetts. Tyco US is registered to conduct business in California. All acts and omissions of Tyco US as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh products at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, Tyco US did business in California.

7. Defendant, TYCO INTERNATIONAL LTD. ("Tyco") (d/b/a Covidien, Inc.) is a company incorporated in Massachusetts with a registered agent in the Commonwealth with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts. Tyco is the parent company for Defendants TIGSA, through its subsidiaries, engaged in the healthcare

business. All acts and omissions of Tyco as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh devices at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, Tyco did business in California.

8. Defendant TYCO INTERNATIONAL GROUP S.A., ("TIGSA") (d/b/a Covidien, Inc.) is a Delaware limited partnership with a registered agent in Delaware limited partnership with its principal place of business at 15 Hampshire Street, Mansfield, Bristol County, Massachusetts. TIGSA is a holding company and wholly owned subsidiary of Tyco that, through its subsidiaries, engaged in the healthcare business. All acts and omissions of TIGSA as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh devices at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, TIGSA did business in California.

9. Defendant, SURGICAL SOLUTIONS GROUP ("Covidien Surgical") is a Delaware corporation with its principal place of business in Colorado, and is a wholly owned subsidiary of Covidien Ltd. All acts and omissions of Covidien Surgical as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Covidien Surgical did business in California.

10. Defendant, UNITED STATES SURGICAL CORP. ("U.S. Surgical") is a Delaware corporation with its principal place of business in Connecticut, and is a wholly owned subsidiary of Covidien plc. U.S. Surgical is registered to do business in California. It also shares the same corporate directors as Covidien US. All acts and omissions of U.S. Surgical as described herein including but not limited to those resulting in the design, manufacture, marketing, labeling,

distribution, sale and placement of its hernia mesh products at issue in the instant suit into Santa Clara County, California, were done by its agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, U.S. Surgical did business in California.

11. Defendant SOFRADIM PRODUCTION SAS ("Sofradim Production") is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Sofradim as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

12. Defendant SOFRADIM CORP. ("Sofradim") is a company with its principal place of business in Mansfield, Bristol County, Massachusetts and offices in Wrentham, Norfolk County, Massachusetts. All acts and omissions of Sofradim Corp. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

13. Defendant MEDTRONIC USA INC. and MEDTRONIC plc f/k/a Medtronic Inc. & Covidien plc, (collectively referred to as "MEDTRONIC") is a corporation that is incorporated under the laws of the State of Minnesota, with offices and facilities at 12 Gill Street, Woburn, Middlesex County, Massachusetts and Boston, Suffolk County, Massachusetts. It is the corporate parent/stockholder of COVIDIEN and all of its subsidiaries and entities. All acts and omissions of Medtronic as described herein were done by its agents, servants, employees and/or owners acting in the course and scope of their respective agencies, services, employments and/or ownership.

14. Medtronic, directly and/or through the actions of Covidien has at all pertinent times been responsible for the research, development, design, testing, manufacture, production, marketing, promotion, distribution and/or sale of the Covidien Parietex Mesh described herein.

15. Manufacturing Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Manufacturing Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its hernia mesh products, including the

Covidien Parietex Mesh, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

16. At all relevant times herein, Manufacturing Defendants were engaged in the design, manufacture, production, testing, study, research, training, inspection, labeling, marketing, advertising, sales, promotion, and/or distribution of the Covidien Parietex Mesh. Manufacturing Defendants do business throughout the United States, and at all relevant times hereto, marketed, promoted, warranted, and/or sold their products in the Commonwealth of Massachusetts.

17. Prior to its acquisition by Covidien, Sofradim was a wholly owned, joint stock sole proprietorship of Floreane Medical Implants, S.A., a French corporation.

18. Sofradim and its parent and affiliates were acquired by Covidien or its predecessor and are now wholly owned by Covidien. Since its acquisition by Covidien, Sofradim has been a business unit or division of Covidien. Since its acquisition by Covidien, Sofradim has been referred to as the "Trevoux Plant" of Covidien and is considered a manufacturing facility for the surgical devices business unit of Covidien. Sofradim is registered with the U.S. Food and Drug Administration ("FDA") as an "establishment," which is the functional equivalent of a manufacturing facility or production plant. Covidien or its corporate affiliates are listed with the FDA as the "owner/operator" of Sofradim, which makes Covidien "directly responsible for the activities" of Sofradim. Since the acquisition of Sofradim by Covidien, the officers, managers and employees of Sofradim have been employees of Covidien.

19. James Nathan Lau, M.D., is a surgeon licensed to perform medical treatment and care in the state of California. During all times relevant to this matter, he had privileges to perform medical treatment and did in fact perform procedures at Stanford Hospital in Stanford, California. Upon information and belief, Dr. Lau was responsible for choosing the type of mesh implanted in Mr. Pina, providing him informed consent prior to the hernia repair surgery, and providing Mr. Pina with adequate directions and oversight to ensure aftercare.

20. Defendant Stanford Hospital has its principal place of business in Stanford, California. Stanford Hospital is believed to be a licensed healthcare provider, licensed in the state of California to perform surgeries, administer care and treatment, and prepare, distribute, combine, formulate, and administer medications to patients by way of medical procedure and prescription. Stanford Hospital, through its officers, directors, agents, servants, employees, and representatives, failed to give adequate informed consent to Plaintiff in relation to the mesh implant and failed to adequately perform the procedures relating to mesh implant. Stanford Hospital also employed Dr. Lau and is therefore vicariously liable for his medical negligence.

21. The true names, identities, or capacities, whether individual, associate, corporate or otherwise of defendants, DOES 1 through 100, inclusive, are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. When the true names, identities, or capacities of said factiously designated defendants are ascertained, plaintiff will seek leave of Court to amend this complaint to insert the true names, identifies, and/or capacities of DOE defendants, together with the proper charging allegations against said DOE defendants.

22. Plaintiff is informed and believes, and thereon allege that each of the defendants sued herein as a DOE defendant is responsible in some manner for the acts, omissions, and conduct which proximately resulted and and/or was a substantial contributing factor to Plaintiff's injuries.

23. All references to "Manufacturing Defendants" hereafter shall refer to COVIDIEN, INC., COVIDIEN, LTD., COVIDIEN PLC, COVIDIEN LLC, COVIDIEN HOLDING INC., MEDTRONIC USA, INC., MEDTRONIC PLC, TYCO HEALTHCARE GROUP LP (d/b/a Covidien, LP), TYCO INTERNATIONAL LTD., TYCO INTERNATIONAL GROUP S.A., SURGICAL SOLUTIONS GROUP, UNITED STATES SURGICAL CORP., a division of TYCO HEALTHCARE GROUP LP, SOFRADIM PRODUCTION SAS, and SOFRADIM CORP and DOES 1 through 50.

24. All references to "Medical Defendants" hereafter shall refer to James Nathan Lau, M.D., Stanford Hospital, and DOES 51 through 100.

25. Manufacturing Defendants are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Manufacturing Defendants' design, manufacture, marketing, labeling, distribution, and sale of the Parietex Mesh at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

26. Manufacturing Defendants had a legal duty to ensure the safety and effectiveness of their Parietex Mesh prior to marketing and selling those products for permanent implantation in Plaintiff. Prior to marketing and selling the Parietex Mesh, Defendants were required to weigh the reasonably knowable risks against the benefits of the device's design and to consider all information that may bear on the safety and efficacy of the design, including the gravity, severity, likelihood, and avoidance of the dangers associated with that design. In addition to making these assessments, the Defendants were required to weigh the benefits against the knowable risks to ensure that the risks do not outweigh the benefits and to mitigate any known or knowable risks through providing adequate warnings and instructions and adequately communicating those warnings and instructions to device users. Defendants had an obligation not to release a product that posed greater risks or more frequent, more severe, or longer lasting risks, than other devices sold for the same use. Because implantation of Defendants' Parietex Mesh is an elective procedure intended to treat non-life-threatening conditions and creates the potential for serious, life-altering complications such as those experienced by Plaintiff, the risks of the Parietex Mesh outweigh any purported benefits, both generally and specifically with respect to the Plaintiff in this case.

27. Defendants are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale, and placement of its Parietex Mesh, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

28. At all relevant times herein, Defendants were engaged in the design, manufacture, production, testing, study, research, training, inspection, labeling, marketing, advertising, sales, promotion, and/or distribution of Parietex Mesh. Defendants at all relevant times hereto, marketed, promoted, warranted, and/or sold their products in the state of California and throughout the United States.

JURISDICTION AND VENUE

29. Jurisdiction and venue are proper in this Court pursuant to the Code of Civil Procedure as the facts and circumstances leading to the Plaintiff's injuries occurred in Stanford, California in the County of Santa Clara.

30. At all times relevant hereto, Manufacturing Defendants were engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, hernia mesh products in the State of California and in interstate commerce, for which each derived significant and regular income.

BACKGROUND

31. Manufacturing Defendants designed, manufactured, sold, and/or distributed Mesh Devices for use in the treatment and repair of hernias, including the Covidien Parietex Composite Open Skirt Mesh implanted in Plaintiff.

32. Manufacturing Defendants were jointly responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of Covidien Parietex Mesh, including providing the warnings and instructions and physician training concerning their products.

33. The polymer used in the Parietex Mesh at issue in this Complaint is polyethylene terephthalate, more commonly referred to as polyester (and is also referred to as polyethylene, "PE," "PET" and/or "Dacron").

34. The polyester mesh component of the Parietex Mesh is covered on one side with a collagen coating derived from animal skin (bovine or porcine), polyethylene glycol and glycerol, the purpose of which was to prevent or minimize adhesion to the internal organs and viscera.

35. The Parietex Mesh was cleared for marketing pursuant to the FDA's premarket notification process, which is also referred to as the "510(k)" process. Medical devices that enter the market through the 510(k) process are not "approved" by the FDA and devices are not formally reviewed for safety or efficacy by the FDA under the 510(k) process. Under the 510(k) process, the FDA does not evaluate the product's safety or effectiveness. The Parietex Mesh has never been formally reviewed for safety or efficacy by the FDA. The Parietex Mesh has never been determined to be safe or effective by the FDA. The Parietex Mesh has never been through the FDA's more rigorous Premarket Approval Process and thus has never been "approved" by the FDA.

36. The polyester polymer used in the design of Parietex mesh is more brittle and significantly more susceptible to fatigue fracture, breakage, fragmentation and other mechanical failures than alternative polymers, including but not limited to polyvinylidene fluoride (PVDF). Peer-reviewed, published literature prior to the introduction of Defendants' PET mesh in the U.S. concluded that "Polyester mesh should no longer be used for incisional hernia repair." Leber, et al. *Long-term complications associated with prosthetic repair of incisional hernias*. **Arch Surg.** 1998; 133(4):378-82. Subsequent literature observed that "the use of PET in hernia surgery is at least questionable in respect to the obligate long-term degradation of this polymer," Klosterhalfen, et al., *Polymers in hernia repair – common polyester vs. polypropylene surgical meshes*. **J. Materials Science** 35:4769-4776 (2000), that "[i]t has also been reported that patients with polyethylene mesh implants have higher incidences of wound-healing complications, fistula and seroma formation and higher incidences of hernia recurrence as compared to polypropylene meshes" and that "due to the loss of stability and the reported mesh-related complications, polyethylene meshes nowadays do not seem fully suitable for a permanent reinforcement of the abdominal wall." Schumpelick, et al. *Light weight meshes in incisional hernia repair*. **J. Minim Access Surgery**. 2006;2(3):117-23.

37. The polyester material used in the Parietex Mesh is susceptible to degradation by hydrolysis, oxidation and/or enzymatic degradation. *See, e.g.*, Smith, et al. *The enzymatic degradation of polymers in vivo*. **J Biomed Mater Res** 1987; 21: 991-1003 (demonstrating degradation of polyester by certain enzymes); Riepe, et al. *Long-term in vivo alterations of polyester vascular grafts in humans*. **Eur J Vasc Endovasc Surg.** 1997;13(6):540-8 (Study of explanted polyester implant devices demonstrating in vivo hydrolytic degradation with scission of macromolecular chains and loss of strength); King, et al. *Microstructural changes in polyester biotextiles during implantation in humans*. **Journal of Textile and Apparel, Technology and Management**. 2001;1(3):1-8 (demonstrating biodegradation and loss of mechanical strength of polyester implants); Schumpelick, *supra* ("One problem of polyethylene meshes is their degradation, which leads to a reduced mechanical stability after 10 years."); Robinson, et al. *Major mesh-related complications following hernia repair: events reported to the Food and Drug Administration*. **Surg Endosc.** 2005; 19(12): 1556-60 ("Incorporated PET can be degraded hydrolytically, resulting in an increased brittleness of the polymer with loss of the mechanical features."); Voskerician, et al. *Effect of biomaterial design criteria on the performance of surgical meshes for abdominal hernia repair: a pre-clinical evaluation in a chronic rat model*. **J Mater Sci Mater Med.** 2010;21(6):1989-95 ("While materials such as PP and PTFE will not undergo hydrolytic degradation, PET, a polyester, will. Further, PET is also susceptible to oxidative degradation due to its ester groups, enhanced by a supplementary degradation mechanism common to all polymers, the direct oxidation by the host. The latter degradation mechanism is the result of host generated molecular species culminating with a foreign body reaction characterized by a continuous process of frustrated phagocytosis by the foreign body giant cells."); Klosterhalfen, et al., *Pathology of traditional surgical nets for hernia repair after long-term implantation in humans*. **Der Chirurg** 2000:71:53-51 (microscopic examination of fragmented and fractured Mersilene (multifilament polyester) mesh after explantation showed pronounced splitting and degradation of polyester fibers). The individual polyester fibers that make up the PET mesh are unreasonably

susceptible to degradation. The gamma irradiation sterilization of the PET produces free radicals that contribute to degradation before implant.

38. The polyester material used in the PET devices incites inflammation and heightened foreign body response, which increases the risks of post-operative complications. Jin, et al., *Human peritoneal membrane controls adhesion formation and host tissue response following intra-abdominal placement in a porcine model*. **J. Sur. Res.** 2009;156(2):297-304 (noting polyester-collagen composite had higher foreign body reaction than other materials); Zinther, et al. *Shrinkage of intraperitoneal onlay mesh in sheep: coated polyester mesh versus covered polypropylene mesh*. **Hernia**. 2010;14(6):611-615 (noting statistically significant increase in shrinkage rate for Parietex versus covered polypropylene mesh and further noting histology showed "marked inflammatory reaction with giant cells adjacent to the polyester filaments, which was absent in the polypropylene specimens"); Orenstein, et al. *Comparative analysis of histopathologic effects of synthetic meshes based on material, weight, and pore size in mice*. **J Surg Res.** 2012;176(2):423-9 ("[P]olyester-based meshes appear to create a local hostile environment with marked foreign body reaction and chronic inflammatory response" and "[o]f the five synthetic meshes implanted, the polyester-based mesh was the greatest inducer of inflammation and appeared to impose severe chronic foreign body reaction."); Nguyen, et al., *Influence of a new monofilament polyester mesh on inflammation and matrix remodeling*. **J. Invest. Surg.** 2012;25(5):330-9 (noting heightened inflammatory response with multifilament polyester material both at molecular level and histologically and recognizing the potential clinical implantations "as there is a higher associated risk for postoperative complications and delayed wound healing in the setting of a persistent and prolonged inflammatory response after mesh implantation."); van 't Riet, et al. *Prevention of adhesion to prosthetic mesh: comparison of different barriers using an incisional hernia model*. **Ann Surg.** 2003;237(1):123-128 ("in the group with Parietex mesh, a more severe inflammatory reaction was found, with the presence of many admixed inflammatory cells and microabscesses (grade 3 on the inflammation grading scale)."); Voskerician, *supra* (observing host tissue response elevated and arrested in a chronic inflammatory phase in the presence of PET mesh).

39. The polyester polymer used in the PET mesh design is significantly more susceptible to loss of mechanical strength over time than alternative materials. Robinson, et al. *Major mesh-related complications following hernia repair: events reported to the Food and Drug Administration*. **Surg Endosc.** 2005; 19(12): 1556-60 ("A significant disadvantage of polyester is loss of mechanical strength over time…, which may lead to hernia recurrence. Polyester is not commonly implanted in the United States, and its continued use for incisional hernia repair has been questioned.").

40. Due to the hydrophilic nature of the PET mesh, the strands of polyester attract and retain bodily fluids, resulting in excessive swelling of the mesh, further increasing the weight and density of the mesh after implant and thus the foreign body load, which increases and prolongs the inflammatory and foreign body reaction to the PET mesh.

41. The fragmentation or flaking-off of particles of the PET fibers exacerbates inflammation and encourages a prolonged and excessive foreign body reaction. This chronic and excessive inflammatory and foreign body reaction, in turn, exacerbates the degradation of the mesh fibers in a vicious cycle. The degradation and fragmentation of the fibers within the PET mesh can lead to the total loss of functionality of the mesh.

42. It has long been scientifically established that the spaces within the construct of a mesh implant had to be large enough to allow the body's natural infection defenses to remove bacteria. Bacteria are much smaller than immune cells and can "hide" if the spaces within the mesh construct are too small to allow infiltration by immune cells, such as the spaces within the multifilamentous structure of the Parietex Mesh. Osterberg. *Influence of capillary multifilament sutures on the antibacterial action of inflammatory cells in infected wounds*. **Acta Chir Scand.** 1983;149(8):751-7 ("Bacterial which are enclosed in the interstices of multifilament suture material, and protected from the phagocytic activity of leukocytes, can sustain and prolong an infection." "The ability of capillary multifilament suture materials to enclose bacteria within their interstices has been demonstrated." "Bacteria enclosed in the interstices of suture thread are protected from phagocytosis – the leukocytes cannot penetrate into these interstices as easily as the bacteria.").

43. Published scientific literature establishes that multifilament materials, such as the Parietex Mesh, are inappropriate and unreasonably dangerous for use in implantable medical devices. Alexander et al. *Role of suture materials in the development of wound infection*. **Ann Surg.** 1967;165(2):192-9 ("[a]ppreciably more infection resulted when these materials were implanted in a braided…or twisted multifilament form…with the same number of organisms." "In all of the experiments, monofilament suture material withstood contamination better than the same kind of multifilament material. Perhaps the bacteria were better able to maintain a defense against phagocytic activity once they had gained entrance to the interstices of a multifilament suture." "It would appear from the results of these experiments that the use of monofilament material of practically any type is preferable to the use of multifilament suture material in contaminated wounds."); van Winkle et al. *Effect of suture materials on healing skin wounds*. **Surg Gynecol Obstet.** 1975;140(1):7-12 ("It was our observation that monofilament sutures were superior to multifilament sutures with regard to the incidence of wound infection."); Amid. *Classification of biomaterials and their related complications in abdominal wall surgery*. **Hernia**. 1997;1(1):15-21 ("Type III prostheses [microporous prostheses with multifilament or microporous components] are similar to braided suture materials, and by harboring bacteria can promote their growth, likewise resulting in biomaterial-related infection."); Leber, *supra* (multifilament polyester material was associated with higher rates for all types of major complications, including fistula and infection, and greater length of hospital stays due to complications than all other mesh designs); Falagas, et al. *Mesh-related infections after hernia repair surgery*. **Clin Microbiol Infect.** 2005;11(1):3-8 ("the use of multifilament polyester mesh resulted in a higher incidence of infection, small bowel obstruction and enterocutaneous fistula formation than the use of other types of mesh (knitted monofilament polypropylene, polytetrafluoroethylene or woven polypropylene)."); Narkhede, et al. *Postoperative Mesh Infection-Still a Concern in Laparoscopic Era*. **Indian J Surg.** 2015;77(4):322-6 ("multifilament such as polyester…significantly increase bacterial persistence or spreading in the infected area in contrast to monofilament polypropylene and lightweight meshes."); van't Riet, *supra* (Parietex group associated with significantly higher inflammation than other mesh types and

57% infection rate versus 0% in control group; "in the current study, Parietex composite mesh was more easily infected than the other meshes and showed a stronger inflammatory response. With infection and increased inflammatory reaction, concurrent increase of the surface of the mesh that was covered by adhesions was seen.").

44. Implantable materials consisting of multifilaments, such as the Parietex Mesh, have long been known scientifically and medically to have a dangerous, undesirable "capillary" effect whereby immobile bacteria are absorbed from surrounding bodily fluids and transported within the filaments. *See, e.g.*, Blomstedt et al. *Suture material and bacterial transport. An experimental study*. **Acta Chir Scand.** 1977;143(2):71-3 ("The in vitro experiment shows that immobile bacteria can be transported inside multifilament suture materials and that the capillary and fluid absorption properties are of significance for the spreading. There are indications of a correlation between the capillarity of the suture material and the frequency and speed of the transport of bacteria. The experiment also shows that immobile bacteria in vivo are transported inside multifilament materials. This way of transport is of significantly greater importance than the one on the surface of the thread. It seems probable that the defense against bacteria is considerably reduced inside the thread compared with that of the surrounding tissues."); Osterberg & Blomstedt. *Effect of suture materials on bacterial survival in infected wounds. An experimental study.* **Acta Chir Scand.** 1979;145(7):431-4 ("It would appear that the physical configuration of the suture thread is an important factor in [the suture's resistance to early development of bacterial infection], the infection rate being higher for multifilament materials with a high capillary capacity than for non-capillary threads.")

45. The propensity of multifilament material for bacterial adherence leads to biofilm formation which inhibits medication or the body's immune response to rid the infection and impairs proper tissue ingrowth. Engelsman, et al., *Morphological aspects of surgical meshes as a risk factor for bacterial colonization*. **Br J Surg.** 2008; 95(8):1051-9 ("This study has shown that…multifilament meshes induced significantly denser biofilm growth than monofilament counterparts; this could be related to the presence of niches between the filaments"… "Treatment of

mesh infections is difficult, as the organisms hide in niches. Rough surfaces and niches provide an increased surface area and more contact points, enabling solid adhesion of microorganisms to the surface of the prosthetic device. All microorganisms prefer to adhere in the niches between the filaments of a multifilament yarn."); Halaweish, et al. *Novel in vitro model for assessing susceptibility of synthetic hernia repair meshes to Staphylococcus aureus infection using green fluorescent protein-labeled bacteria and modern imagine techniques*. **Surg Infect (Larchmt)**. 2010; 11(5):449-54 ("The more complex the architecture, the greater the surface area of the material as well as the presence of niches that bacteria can use as a haven from tissue ingrowth, neovascularization, antibiotics, and the host inflammatory response…. Other studies have shown that bacteria have a propensity to attach to and produce more biofilm in the niches between the filaments."); Sadava, *supra* (observing that Parietex meshes demonstrated more biofilm formation than monofilament polypropylene meshes, and that the majority of biofilm identified with Parietex meshes occurred within the filaments of the Parietex meshes); Narkhede, *supra* ("Bacterial attachment, proliferation and biofilm formation on the surface of synthetic materials are essential steps in the sequence leading to mesh infections….Biofilm is formed following the attachment of a community of bacteria to a surface and subsequent release of an exopolysaccharide matrix. This 'biofilm skeleton' protects the bacteria from antibiotics and the host defence system, thus facilitating persistent infections and challenge attempts to eradicate these infections."); Jacombs, et al. *Biofilms and effective porosity of hernia mesh: are they silent assassins?* **Hernia.** 2020;24(1):197-204 (noting potential for biofilm to reduce porosity of hernia mesh and lead to multiple, long-term complications, including late, low-grade localized sepsis, swelling, erythema, late seroma formation, fistula formation, and mesh-capsule deformity and mesh failure).The surface area of multifilament material is significantly higher than that of monofilament materials, which increases the adherence of bacteria to the material and increases the foreign body response and inflammatory response to the material. Halaweish, *supra* ("It is estimated that the surface area of multifilament material is 157% higher than that of monofilament materials…."); Schumpelick, *supra* ("[D]espite clinical advantages, there is still concern about the use of multifilaments with

regard to a possible potentiation of infection through the interstices of the braided structure…. [T]he increased surface area promotes the persistence of bacteria in the implant bed."); Klosterhalfen B, Klinge U. *Biocompatibility of biomaterials-Histological aspects*. **In: Schumpelick V (ed.). Incisional Hernia**. Springer 1999:198-216 ("Another important factor influencing the activity of inflammation in the interface is the surface or contact area between mesh and recipient tissues. Our studies demonstrated that an increase in the plane area of the mesh by using multifilaments directly enhances the activity of the inflammatory reaction…Parietex meshes show a stress level which exceeds the tolerance level of the interface tissues, leading to cell damage and subsequent tissue repair…. The tissue reaction is defined in a dose-dependent manner, meaning an activation of inflammation and an increase in irritation with the increase in weight *(g/m²)* and surface area (multi- or monofilaments, pore size) in contact with the mesh.) …. The use of heavy weight meshes such as…Parietex should be avoided, particularly in children and young adults.").

46. The propensity of the hydrophilic, multifilament mesh for chronic bacterial proliferation and biofilm formation results not only in clinically relevant (symptomatic) infections, but also clinically latent infections which cause no clinical symptoms, but which nonetheless impede proper ingrowth and appropriate biologic response to the material, and lead to recurrence and adhesion to internal organs and viscera. Smith G, Chetter I. *Infection in prosthetic material*. **Surgery (Oxford)**. 2015;33(11):559-564 (observing that late infection of surgical implants "are often indolent in nature and are frequently caused by less virulent bacterial strains often presenting with a continually discharging sinus but no clinical signs of sepsis and often negative cultures."); Mangir, et al. *Complications related to use of mesh implants in surgical treatment of stress urinary incontinence and pelvic organ prolapse: infection or inflammation?* **World J Urol.** 2020;38(1):73-80 ("Mesh infection is also thought to be asymptomatic (silent), but it can actually interfere with the successful integration of the mesh into host tissues leading to mesh exposure in some cases. A positive bacterial culture was obtained from 77% of the vaginal meshes explanted due to pain, mesh erosion, mesh infection, and recurrent UTIs. Therefore, mesh-related infections can be a solitary

complication of vaginal mesh surgeries, and at the same time, it can be one of the factors in a multifactorial process underlying other mesh-related complications such as exposure and pain.").

47. The collagen coating of the Covidien Parietex Mesh, was intended to limit adhesions to internal organs and viscera, did not limit or prevent adhesions to the internal organs and viscera as intended and as represented, and instead only increased the risks associated with the polyester mesh, including the risks of adhesion and scarification. Liu, et al. *Comparison of coated meshes for intraperitoneal placement in animal studies: a systematic review and meta-analysis*. **Hernia**. 2019;28:1-9. (Meta-analysis of published literature regarding adhesion prevision of Parietex Composite, observing "[o]ur meta-analysis showed no significant difference to be found between [Parietex Composite] and [bare polypropylene] mesh in animal experiments using random effects model…."); Winny, et al. *Adhesion prevention efficacy of composite meshes Parietex®, Proceed® and 4DryField® PH covered polypropylene meshes in an IPOM rat model*. **Int J Med Sc.** 2016;13(12):936 (Parietex Composite showed no significantly reduced adhesion scores compared to uncoated control); van't Riet, *supra* (Parietex group associated with significantly higher inflammation than other mesh types and 57% infection rate versus 0% in control group; "in the current study, Parietex composite mesh was more easily infected than the other meshes and showed a stronger inflammatory response. With infection and increased inflammatory reaction, concurrent increase of the surface of the mesh that was covered by adhesions was seen.").

48. Defendants have never obtained any studies, data, testing or other evidence to demonstrate that the collagen coating of the Parietex Mesh provided any clinical advantage to patients as compared with the "bare" polyester mesh.

49. The addition of the collagen coating to the Parietex Mesh increased the density of the device and thus increased the foreign body and inflammatory reaction to the device.

50. Contrary to Defendants' claims that the collagen coating decreased the inflammatory response, the degradation or phagocytosis of the collagen coating incites an intense foreign body reaction and inflammation, which in turn further exacerbates the degradation of the polyester material. Grotenhuis, et al. *In vitro model to study the biomaterial-dependent reaction of*

macrophages in an inflammatory environment. **Br. J. Sur.** 2014; 101(8):983-92 (noting PET mesh "evoked the highest absolute production of proinflammatory cytokines" and observing that "[t]his acute reaction can be explained by phagocytic activity of macrophages, trying to break down and digest the thin collagen layer" and noting that polyester with collagen "material itself has a great influence on the reaction of macrophages."); Zinther, *supra* ("The excess shrinkage seen with the coated polyester mesh may be due to the presence of an additional degradable coating. The coating may induce an excessive inflammatory reaction and, thus, a greater degree of shrinkage. The inflammatory response in sheep is similar to the inflammatory response in humans. Consequently, findings can be applied to the clinical setting.").

51. The collagen coating of the Parietex Mesh swells between 200% and 500% after implantation, which significantly increases the foreign body load and thus further increases the foreign body response and inflammation. This swelling of the collagen coating also impedes tissue ingrowth and can cause the tacks or fixation devices to be pulled from the tissue, further impeding proper tissue ingrowth and leading to deformation of the mesh.

52. The hydrophilicity of the collagen coating attracts moisture and fluids and contributes to the Parietex Mesh being unreasonably susceptible to becoming adhered to internal organs and viscera.

53. The collagen coating of the Parietex Mesh was unreasonably susceptible to damage, ripping, or tearing prior to or during implantation and after implantation, which would expose bare polyester fibers to internal organs and viscera, thereby contributing to the Parietex Mesh being unreasonably susceptible to becoming adhered to internal organs and viscera.

54. Plaintiff underwent surgery to repair an incisional ventral hernia on July 9, 2018, at Stanford Hospital in Stanford, California. Dr. James Lau performed the operation using a Covidien Parietex Composite Open Skirt Mesh (REF: PCO252OSX, PRB2363X). Dr. Lau failed to properly place and secure the Covidien Parietex Mesh in Plaintiff. Prior to the surgery, Dr. Lau failed to provide Plaintiff with adequate informed consent regarding the Covidien mesh and the surgery. After the surgery, Dr. Lau failed to provide Plaintiff with adequate post-operation care instructions.

55. Plaintiff's Covidien Parietex Mesh developed recurrent fluid collections which had required interventional radiology drainage. Because this had happened multiple times his healthcare providers were concerned the mesh had become chronically infected and recommended that he undergo exploratory laparotomy and possibly have the mesh removed.

56. Plaintiff returned to Stanford Hospital on March 4, 2022 for surgery with Dr. Jamie Tung. The surgery revealed the mesh was significantly infected with multiple abscess cavities of foul-smelling, purulent fluid on the surface of the mesh. The small bowel had a small defect just below the mesh. The mesh was densely adhered to the inside wall of the stomach lining. The infected mesh was removed, and Plaintiff's small bowel was resected to remove the defect.

57. On November 21, 2022, Plaintiff returned to Sanford Hospital for a second exploratory laparotomy. A fistula had developed, creating a connection between Plaintiff's small bowel to the abdominal wall. The fistula was caused by a previously placed tack used to secure the Covidien Parietex Mesh when it was first implanted. Once again dense adhesions had formed which needed to be taken down. A second resection of the small bowel was performed of the section with the fistula. Three other serosal injuries were discovered and repaired.

58. Plaintiff has suffered and continues to suffer from injuries due to the acts and omissions of the Defendants named herein.

COUNT I:
STRICT PRODUCTS LIABILITY — INADEQUATE WARNING
(Against Manufacturing Defendants)

59. Plaintiff re-alleges and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

60. At the time the Covidien Parietex Mesh was implanted in Plaintiff, the warnings and instructions provided by Defendants were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purpose for which it was intended, and Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

61. The Manufacturing Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers as to the risks of the Covidien Parietex Mesh.

62. The Manufacturing Defendants failed to properly and adequately warn and instruct Plaintiff and his health care providers with regard to the inadequate research and testing of the Covidien Parietex Mesh.

63. The Manufacturing Defendants failed to properly and adequately warn and instruct Plaintiff or his health care providers regarding the lack of a safe, effective procedure for removal of the Covidien Parietex Mesh in the event of complications or device failure.

64. Defendants expected and intended the Covidien Parietex Mesh to reach users such as Plaintiff in the condition in which the products were sold.

65. Plaintiff and his physicians were unaware of the defects and dangers of Covidien Parietex Mesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Covidien Parietex Mesh.

66. The Manufacturing Defendants' Instructions for Use provided with the Covidien Parietex Mesh expressly understates and misstates the risks known to be associated with the Covidien Parietex Mesh by, e.g., stating that the "contraindications" for Covidien Parietex Mesh are the "usual contraindications for the use of wall reinforcements," and that the complications associated with Covidien Parietex Mesh are the same as other "complications arising from wall construction with mesh" or those "typically associated with surgically implanted materials." Manufacturing Defendants' Instructions for Use provided with the Covidien Parietex Mesh expressly understates and misstates the risks known to be associated specifically with the Covidien Parietex Mesh by representing that "the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera." The multifilament polyester, hydrophilic design of Covidien Parietex Mesh causes or increases the risks of numerous complications, including embrittlement and loss of mechanical stability, degradation, fragmentation and fraying, biofilm formation, immunologic response, increased risk for infection, abscess and fistula formation, and increased risk of chronic inflammatory reaction and foreign body response. The

animal collagen coating of the Covidien Parietex Mesh products, which was intended and expressly represented to minimize adhesions, attracts moisture and fluids and sticks to viscera, is unreasonably susceptible to damage, exacerbates the inflammatory response to the device, and is only present for days, leaving the bare polyester material in direct contact with internal organs and viscera and leading to the unreasonable risk of adhesion to organs and viscera, serosal damage, fistula formation and erosion into internal organs. Manufacturing Defendants provided no warning to Plaintiff or his physicians about the increased risks associated with the design of the Covidien Parietex Mesh, including those identified above.

67. The Manufacturing Defendants' Instructions for Use for the Covidien Parietex Mesh failed to adequately warn Plaintiff or his physicians of numerous risks which Manufacturing Defendants knew or should have known were associated with the Covidien Parietex Mesh, including but not limited to the risks of the product's inhibition of tissue incorporation, chronic pain, inflammation, fistula formation, abscess formation, biofilm formation, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, fragmentation, deformation, adhesion to internal organs and viscera, erosion through tissue and viscera, serosal damage, tissue necrosis, intestinal obstruction, hernia incarceration or strangulation, or rupture/fracture of the mesh.

68. Manufacturing Defendants failed to adequately instruct or warn Plaintiff or his physicians that in the event of infection, the Covidien Parietex Mesh must be removed in its entirety, which may be difficult or impossible due to the design of the product.

69. Manufacturing Defendants failed to adequately instruct or warn Plaintiff or his physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

70. Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the necessary surgical removal of the Covidien Parietex Mesh in the event of complications would leave the hernia unrepaired and would necessitate further medical treatment to attempt to repair the same hernia that the failed product was intended to treat.

71. Manufacturing Defendants failed to adequately warn or instruct Plaintiff or his physicians that the surgery required to remove the Covidien Parietex Mesh in the event of complications would obviate any purported benefit associated with implantation, and would involve additional, significant risks to the patient.

72. With respect to the complications that were listed in the Manufacturing Defendants' product insert warnings, Manufacturing Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Covidien Parietex Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

73. If Plaintiff and/or his physicians had been properly warned of the defects and dangers of Covidien Parietex Mesh, and of the frequency, severity and duration of the risks associated with the Covidien Parietex Mesh, Plaintiff would not have consented to allow the Covidien Parietex Mesh to be implanted.

74. Manufacturing Defendants failed to adequately communicate the warnings of the risks associated with Covidien Parietex Mesh to Plaintiff's physicians.

75. The Manufacturing Defendants are strictly liable in tort to Plaintiff for their wrongful conduct described herein.

76. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiffs have been injured, sustained severe and permanent mental and physical pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

77. Manufacturing Defendants are equitably estopped from asserting a learned intermediary defense due to Manufacturing Defendants' fraudulent concealment, through affirmative misrepresentations and omissions of the risks and defects associated with the Covidien Parietex Mesh, including the severity, duration and frequency of risks and complications. Manufacturing Defendants affirmatively withheld and/or misrepresented facts concerning the safety

of the Covidien Parietex Mesh, including but not limited to adverse data and information from studies and testing conducted with respect to Covidien Parietex Mesh that showed the risks and dangers associated with Covidien Parietex Mesh were unreasonable, which were intentionally withheld from Plaintiff and his physicians. As a result of Manufacturing Defendants' misrepresentations and concealment, Plaintiff and his physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Manufacturing Defendants.

WHEREFORE, Plaintiff Antonio Pina demands judgment against Manufacturing Defendants, and each of them, as hereinafter set forth.

COUNT II:
NEGLIGENCE
(Against Manufacturing Defendants)

78. Plaintiff re-alleges and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

79. Manufacturing Defendants had a duty to individuals, including Plaintiff, to use reasonable and ordinary care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Covidien Parietex Mesh, as well as in the instruction and training of physicians to implant the Covidien Parietex Mesh and/or to properly treat complications associated with the Covidien Parietex Mesh.

80. Manufacturing Defendants knew, or in the exercise of reasonable care should have known, that Covidien Parietex Mesh were defectively and unreasonably designed, was unreasonably dangerous and likely to injure patients in whom Covidien Parietex Mesh were implanted. Manufacturing Defendants knew or should have known that Plaintiff and his physicians were unaware of the dangers and defects inherent in the Covidien Parietex Mesh.

81. Manufacturing Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing and distribution of the Covidien Parietex Mesh.

82. Manufacturing Defendants breached their duty of care by:

a. Failing to design the Covidien Parietex Mesh so as to avoid an unreasonable risk of harm to the patients in whom the product was implanted, including the Plaintiff.

b. Failing to use reasonable care in the testing and study of the Covidien Parietex Mesh so as to avoid an unreasonable risk of harm to patients in whom the Covidien Parietex Mesh product was implanted, including the Plaintiff.

c. Withholding adverse information regarding the Covidien Parietex Mesh within their knowledge, including but not limited to information from testing or study of Covidien Parietex Mesh and/or devices with similar design features and adverse event reporting demonstrating unacceptable risks, and thereby preventing Plaintiff and his physicians from understanding the risks associated with the Covidien Parietex Mesh.

d. Failing to adequately instruct, train or warn physicians regarding the use of the Covidien Parietex Mesh, the risks associated therewith, including the frequency, severity and duration of such risks, and the appropriate treatment for complications associated with Covidien Parietex Mesh.

e. Negligently or carelessly designing, marketing, labeling, testing, packaging and/or selling the Covidien Parietex Mesh; and/or

f. Negligently or carelessly failing to properly instruct and train physicians in the implantation and/or removal of Covidien Parietex Mesh and in the appropriate treatment of complications associated with Covidien Parietex Mesh.

83. The reasons that Manufacturing Defendants' negligence caused the Covidien Parietex Mesh to be unreasonably dangerous and defective include those described herein, which include but are not limited to:

a. The multifilament design of Covidien Parietex Mesh is heavier and denser than alternative designs, which increases the foreign body load and creates or contributes to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction and inadequate tissue incorporation, leading to scarification, adhesion and recurrence.

b. The multifilament design of Covidien Parietex Mesh has a significantly higher surface area and lower porosity and attracts and retains bodily fluids, which increases the foreign body load and creates or contributes to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction and inadequate tissue incorporation, leading to scarification, adhesion and recurrence.

c. The multifilament design of Covidien Parietex Mesh and the hydrophilic properties of the PET devices attract and retain bodily fluids, which leads to infection, abscess formation and other complications.

d. The multifilament design of Covidien Parietex Mesh and the hydrophilic properties of the PET devices provide a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate, leading to serious infection, fistula formation and abscess and causing biofilm formation that inhibits the body's immune response and impedes proper tissue ingrowth.

e. The hydrophilic polyester of the PET devices becomes brittle and is unreasonably susceptible to fatigue fracture, breakage, fragmentation and other mechanical failures than alternative materials.

f. The polymers comprising the Covidien Parietex Mesh are unreasonably susceptible to hydrolytic, oxidative and/or enzymatic degradation.

g. The gamma radiation sterilization of PET products contributes to the degradation of the polyester material.

h. The fibers of the Covidien Parietex Mesh can flake or fragment and lead to chronic and excessive inflammation.

i. The fragmentation or flaking of the fibers contributes to the hydrolytic, oxidative and/or enzymatic degradation of the Covidien Parietex Mesh.

j. The propensity of the Covidien Parietex Mesh for bacterial infiltration and inflammation contributes to the hydrolytic, oxidative and/or enzymatic degradation of the Covidien Parietex Mesh.

k. The products were insufficient to withstand normal abdominal forces, which resulted in recurrent hernia formation and/or rupture and deformation of the mesh itself.

l. The collagen coating of the Covidien Parietex Mesh failed to minimize or prevent adhesion, the purpose for which it was included in the design and which Manufacturing Defendants expressly represented it would do.

m. The collagen coating of the Covidien Parietex Mesh was unreasonably susceptible to damage or tearing prior to, during or after implantation.

n. The collagen coating of the Covidien Parietex Mesh swells significantly upon implantation which significantly increases the foreign body load and thus further increases the foreign body response and inflammation. This swelling of the collagen coating impedes tissue ingrowth and can cause the tacks or fixation devices to be pulled from the tissue, further impeding proper tissue ingrowth and leading to deformation of the mesh.

o. The hydrophilicity of the collagen coating of the Covidien Parietex Mesh attracts fluids and made the coating unreasonably susceptible to adhesion to internal organs and viscera, serosal damage, fistula formation and erosion into organs.

p. The collagen coating of the Covidien Parietex Mesh was degraded or phagocytized within days, leaving the bare polyester material in direct contact with internal organs and viscera, presenting an unreasonable risk of adhesion, serosal damage, fistula formation and erosion into organs.

84. Manufacturing Defendants also negligently failed to warn or instruct Plaintiff or his physicians regarding the risks and defects associated with the Covidien Parietex Mesh, and failed to adequately communicate such warnings and instructions to Plaintiff or his physicians, including those described herein, which include but are not limited to:

a. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the design elements of Covidien Parietex Mesh potentiate infection, cause fistula formation and abscesses and lead to biofilm formation.

b. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the design elements of Covidien Parietex Mesh lead to an intense inflammatory and chronic foreign body response, preventing adequate tissue incorporation.

c. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the design elements of Covidien Parietex Mesh are susceptible to hydrolytic, oxidative and/or enzymatic degradation.

d. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the Covidien Parietex Mesh becomes brittle and loses mechanical strength and stability.

e. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the hydrophilic collagen coating of Covidien Parietex Mesh would swell between 200% and 500% upon implantation and increase the foreign body load and in turn the foreign body response and impairing adequate ingrowth.

f. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the hydrophilic collagen coating of Covidien Parietex Mesh lasted only days and would leave bare polyester mesh in contact with internal viscera and organs, leading to serosal damage, adhesion to internal organs and viscera, erosion into internal organs and viscera, and fistula formation.

g. The Manufacturing Defendants expressly understated the risks known to be associated specifically with Covidien Parietex Mesh, instead stating that the risks

were the same as any other implantable material. The design elements of the Covidien Parietex Mesh as stated herein cause or increase the risks of numerous complications, including infection, tissue necrosis, fistula and abscess formation, biofilm formation, prevention of adequate incorporation, increased inflammatory reaction and foreign body response, serosal damage, adhesion to internal organs and viscera, and erosion into internal organs and viscera.

h. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of numerous risks which Defendants knew or should have known were associated with Covidien Parietex Mesh, including but not limited to the risks of chronic pain, inflammation, inadequate tissue incorporation, tissue necrosis, immunologic response, dehiscence, biofilm formation, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, intestinal obstruction, hernia incarceration or strangulation, abscess formation, fistula formation, bowel adhesion, bowel erosion, serosal damage to viscera and internal organs, or rupture/fracture of the mesh.

i. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the unusually high rate of infection, fistula formation and abscess associated with the multifilament, hydrophilic polyester mesh.

j. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the risk of chronic inflammation associated with the Covidien Parietex Mesh.

k. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the need for corrective surgery to adjust, remove or revise the Covidien Parietex Mesh in the event of complications.

l. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the need to completely remove the Covidien Parietex Mesh in the event of infection, fistula or abscess, which in many cases may be difficult or impossible due to the design of the product.

m. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the frequency, severity and duration of complications and risks associated with the Covidien Parietex Mesh, particularly those risks known to be associated specifically with the multifilament, hydrophilic polyester material and the hydrophilic animal collagen coating, such as infection, fistula and abscess formation, biofilm formation, chronic inflammatory response, tissue necrosis, lack of incorporation, adhesion to internal organs and viscera, erosion of internal organs, and serosal damage.

n. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the defective features of the Covidien Parietex Mesh design described above.

o. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the Covidien Parietex Mesh expose patients to more risks and different risks than those associated with products with safer feasible alternative designs.

p. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that the risks associated with the Covidien Parietex Mesh are more frequent, severe, longer lasting, and more difficult to treat than those associated with products with safer feasible alternative designs.

q. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that Covidien Parietex Mesh are less effective than feasible, available alternatives.

r. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that Covidien Parietex Mesh puts a patient at a greater risk of requiring additional surgery than feasible, available alternatives.

s. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that use of Covidien Parietex Mesh makes any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives, particularly in the event of infection, abscess or fistula formation or adhesion to or erosion of internal organs.

t. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians of the difficulty in removing Covidien Parietex Mesh after injury, including the fragmented shards of the mesh fibers, which increased risk of future injuries.

u. The Manufacturing Defendants failed to adequately warn Plaintiff or his physicians that removal of the Mesh Devices due to complications may significantly impair the patients' quality of life and may not result in complete resolution of their injuries.

85. Manufacturing Defendants knew or should have known that its failure to exercise ordinary care under the circumstances in the manufacture, design, packaging, labeling, warnings, instructions, sale, marketing, distribution and training of physicians to implant the Covidien Parietex Mesh and/or to treat resulting complications would cause foreseeable harm, injuries, and damages to individuals implanted with Manufacturing, including the Plaintiff.

86. Manufacturing Defendants knew, or in the exercise of reasonable care should have known, that the Covidien Parietex Mesh was defectively and unreasonably designed and was unreasonably dangerous and likely to injure patients in whom they are implanted. Defendants knew or should have known that Plaintiff and his physicians were unaware of the dangers and defects inherent in the Covidien Parietex Mesh.

87. Manufacturing Defendants' negligence was a proximate cause of the damages and injuries to Plaintiffs.

88. As a direct and proximate result of Manufacturing Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Covidien Parietex Mesh, and Manufacturing Defendants' negligence in failing to adequately communicate warnings and instructions for Covidien Parietex Mesh, Plaintiff has been injured, sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages including, but not limited to medical expenses, lost income, and other damages.

WHEREFORE, Plaintiff Antonio Pina demands judgment against Manufacturing Defendants, and each of them, as hereinafter set forth.

COUNT III:
FRAUDULENT CONCEALMENT
(Against Manufacturing Defendants)

89. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

90. In marketing and selling the device, Manufacturing Defendants, and each of them, concealed material facts from Plaintiff and his health care providers.

91. Manufacturing Defendants, and each of them, concealed material facts regarding the Covidien Parietex Mesh including, but not limited to, the following:

a. That the device was unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;

b. That the device posed dangerous health risks in excess of those associated with the use of other similar devices;

c. That there were additional side effects related to implantation and use of this device that were not accurately and completely reflected in the warnings associated with the devices; and

d. That the device was not adequately tested to withstand normal placement within the human body.

92. Plaintiff and his healthcare providers were not aware of these and other facts concealed by Manufacturing Defendants, and each of them.

93. Manufacturing Defendants, and each of them, are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Manufacturing Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

94. In concealing these and other facts, Manufacturing Defendants intended to deceive Plaintiff and his health care providers as to the true facts regarding the safety and efficacy of the Covidien Parietex Mesh.

95. Plaintiff's healthcare providers did in fact review the product inserts Manufacturing Defendants, and each of them, distributed with the Covidien Parietex Mesh prior to prescribing the product to Plaintiff.

96. Plaintiff and his healthcare providers reasonably and justifiably relied on the above-described concealments by Manufacturing Defendants.

97. This concealment by Manufacturing Defendants of material facts from Plaintiff and his healthcare providers was a substantial factor in Plaintiff's health care providers deciding to use the devices and in Plaintiff's agreement to be implanted with the device. Thus, Manufacturing Defendants' fraudulent concealment was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

98. Plaintiff's physicians would not have prescribed the Covidien Parietex Mesh to Plaintiff had Manufacturing Defendants not concealed the above-described information. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

WHEREFORE, Plaintiff Antonio Pina demands judgment against Manufacturing Defendants, and each of them, as hereinafter set forth.

COUNT IV
EXPRESS WARRANTY
(Against Manufacturing Defendants)

99. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

100. Prior to, on, and after the dates during which Plaintiff was implanted with the Covidien Parietex Mesh, and at all relevant times, Manufacturing Defendants, and each of them, had knowledge of the purpose for which the Covidien Parietex Mesh was to be used, and represented the devices to be in all respects safe, effective, and proper for such purpose. Said

warranties and representations were made to Plaintiff and his treating physicians. Plaintiff and his treating physicians relied on said warranties and representations in deciding to use the device.

101. Manufacturing Defendants used packaging inserts and media advertisements to represent to the medical community and consumers, including plaintiff and his health care providers, that the Covidien Parietex Mesh was safe for its intended use; did not pose serious health hazards when used appropriately; was safer and more effective than alternative mesh devices; had been adequately tested for its intended use; and would not cause injury after implantation.

102. Manufacturing Defendants, and each of them, breached the above-described express warranties and representations in that the Covidien Parietex Mesh did not conform to these express warranties and representations.

103. Prior to, on, and after the dates during which Plaintiff and his physicians purchased and used these devices, Manufacturing Defendants, and each of them, were put on notice of the Covidien Parietex Mesh mesh's inability to conform to these express warranties.

104. Manufacturing Defendants' breach of said express warranties and representations prior to, on, and after the date Plaintiff and his physicians purchased and used the devices was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

WHEREFORE, Plaintiff Antonio Pina demands judgment against Manufacturing Defendants, and each of them, as hereinafter set forth.

COUNT V
MEDICAL NEGLIGENCE
(Against Medical Defendants)

105. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

106. On or about July 19, 2018, Plaintiff Antonia Pina underwent hernia repair surgery and was implanted with the Covidien Parietex Mesh by Defendants James Nathan Lau, M.D. and Stanford Hospital, through their agents and employees, and DOES 51 through 100.

107. In the aforementioned care and treatment of Plaintiff , Defendants James Nathan Lau, M.D. and Stanford Hospital, through their agents and employees, and DOES 51 through 100,

failed to possess, provide, and/or exercise that degree and standard of knowledge or skill that is required to be possessed and exercised by physicians, surgeons, hospitals, nurses, and other health care providers and engaged in said professions in the same locality and defendants, in that said defendants negligently: failed to properly and correctly and timely diagnose Plaintiff's symptoms and conditions; failed to provide adequate informed consent and post-operative directions; failed to properly place the Covidien Parietex Mesh implanted in Plaintiff; failed to render care and treatment to, perform proper surgery upon, and prescribe and administer medications and treatment for the conditions and health and well-being of Plaintiff which was a substantial factor in causing Plaintiff harm.

WHEREFORE, Plaintiff Antonia Pina demands judgment against Medical Defendants, and each of them, as hereinafter set forth.

PUNITIVE DAMAGES ALLEGATIONS
(Against Manufacturing Defendants)

108. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

109. Manufacturing Defendants failed to adequately test and study the Covidien Parietex Mesh to determine and ensure that the products were safe and effective prior to releasing the products for sale for permanent human implantation, and Defendants continued to manufacture and sell Covidien Parietex Mesh after obtaining knowledge and information that the products was defective and unreasonably unsafe. The limited testing and study that was undertaken by Manufacturing Defendants prior to release and after release of the Covidien Parietex Mesh, including but not limited to animal studies and human clinical studies, revealed to Manufacturing Defendants that the risks associated with the Covidien Parietex Mesh were unreasonably frequent and severe and outweighed any purported benefits of the product. The adverse results of those tests and studies were intentionally concealed, or else were misrepresented, by Manufacturing Defendants in order to continue to profit from sales of Covidien Parietex Mesh. Manufacturing Defendants were aware of the probable consequences of implantation of the dangerous and

defective Covidien Parietex Mesh, such as those suffered by Plaintiff. Manufacturing Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Manufacturing Defendants acted intentionally, maliciously and recklessly with regard to the safety of those persons who might foreseeably have been harmed by the Covidien Parietex Mesh, including Plaintiff, justifying the imposition of punitive damages.

110. At all times relevant hereto, Manufacturing Defendants knew or should have known that the Manufacturing Defendants' Covidien Parietex Mesh was inherently dangerous with respect to the risks of serious complications, including but not limited to serious infections and failures, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments, as well as other severe and personal injuries which are chronic or permanent in nature.

111. At all times material hereto, Manufacturing Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Covidien Parietex Mesh, including but not limited to adverse data and information from studies and testing conducted with respect to Covidien Parietex Mesh that showed the risks and dangers associated therewith were unreasonable.

112. Manufacturing Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff or their treating physicians, concerning the safety and efficacy of the Covidien Parietex Mesh.

113. At all times material hereto, Manufacturing Defendants knew and intentionally and/or recklessly disregarded the fact that the Covidien Parietex Mesh caused severe and potentially permanent complications with greater frequency than safer alternative devices or treatments and that necessitate different medical treatment.

114. At all times material hereto, Manufacturing Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Covidien Parietex Mesh, including but not limited to data regarding the frequency, severity and duration of those risks and complications.

115. Notwithstanding their knowledge, Manufacturing Defendants continued to market the Covidien Parietex Mesh to consumers without disclosing the true risk of side effects and complications, or the frequency, severity and duration of those risks.

116. Manufacturing Defendants knew of the defective and unreasonably dangerous nature of the Covidien Parietex Mesh, but continued to manufacture, produce, assemble, market, distribute, and sell the devices so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by the Covidien Parietex Mesh.

117. Manufacturing Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

Wherefore, Plaintiff respectfully requests judgment in her favor and against Manufacturing Defendants for such amount sufficient to punish, penalize and deter Manufacturing Defendants' conduct and any other amounts or relief as may be fair and reasonable under the circumstances.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff prays for relief against all Defendants including, Does 1 through 100, inclusive, on the entire complaint, as follows:

a. General damages according to proof at the time of trial;

b. Special (economic) damages, including without limitation, past and future medical expenses and past and future lost wages according to proof at time of trial.

c. Pre-judgment and post-judgment interest pursuant to the laws of the State of California;

d. Costs of suit incurred herein;

e. Punitive damages solely against Manufacturing Defendants in an amount sufficient to punish them and deter similar conduct in the future;

f. For such further and other relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: May 4, 2023

Respectfully Submitted,

/s/ Troy A. Benes_____
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